

## Strategic Partnership III

### RFA 13-03: CIRM Strategic Partnership III Awards

The purpose of the Strategic Partnership Awards Initiative ("Initiative") is to attract industry engagement and investment in CIRM funded stem cell research. The intent of the Initiative is to create incentives and processes that will: (i) enhance the likelihood that CIRM funded projects will obtain funding for future clinical trials (e.g. follow-on financing), (ii) provide a source of co-funding for the earlier stages of clinical development, and (iii) enable CIRM funded projects to access expertise within pharmaceutical and large biotechnology partners in areas such as discovery, preclinical, regulatory, clinical trial design and manufacturing process development.

This Initiative requires applicants to show evidence of either having the financial capacity to move the project through development or of being able to attract the capital to do so. This may be evidenced by, for example, (i) significant investment by venture capital firms, large biotechnology or pharmaceutical companies, disease foundations and/or through the public markets; and financial statements evidencing significant liquid assets; or (ii) a collaborative research agreement with a large biotechnology or pharmaceutical company. The agreement with the large biotechnology or pharmaceutical company need only cover co-funding and collaboration support for the proposed project (and not future development).

CIRM intends to offer repeat calls under this initiative every 6-9 months. The focus, scope and objective may differ with each solicitation.

### Award Tracks

Strategic Partnership III will have two possible Award tracks, Track A and Track B, as described below. Under this RFA, a for-profit applicant may apply through either Track A or Track B, but not both. Non-profit applicants may only apply under Track A.

#### Track A Awards (RFA 13-03A)

A Track A award will provide funding for a single development project for a single therapeutic candidate per applicant over a project period of up to 4 years. Under Track A, a non-profit Principal Investigator (PI) may submit a single application, and a for-profit organization may submit a single application.

#### Track B Awards (RFA 13-03B: Milestone Payment Pathway)

Track B awards will provide funding for up to five approved development projects per for-profit applicant organization, with funding contingent on successful achievement of the Major Development Milestone for each project, which will be agreed to between CIRM and the applicant in advance of award issuance. Under Track B, a for-profit applicant organization may apply for funding for up to five different development projects, which may be focused on the development of different therapeutic candidates, or the use of a single therapeutic candidate to target distinct, non-overlapping disease indications.

Award Tracks A and B in RFA 13-03 are compared in Table 1:

**Table 1: Features of RFA 13-03 Track A and Track B**

Award Feature	RFA 13-03A (Track A)	RFA 13-03B (Track B)
Applicant Organization	Not-for-Profit or For-Profit	For-Profit
Maximum Amount of Award Funding	Up to \$10M* of Total Project Costs (including indirect & facilities costs)	Up to \$10M of Direct Project Costs per Project
Co-funding Requirement	CIRM: Applicant = 1 to 1	CIRM: Applicant = 1.5 to 1

Number of Applications per Organization	1	Up to 5
Number of Applications per Principal Investigator	1	Up to 3
Readiness	Pre-IND Meeting required (for Preclinical stage Projects) or IND Filed (for Clinical stage Projects) Before Application Deadline (October 21, 2013)	IND Filed Prior to Funding Approval (Q2, 2014)
Award Payment Schedule	Quarterly or Semi-annual Disbursements Throughout 4 Year Period of Award	Only upon Successful Achievement of Major Development Milestone
Commercial Validation Requirements to Demonstrate Financial Strength	Equity and/or Investment of \$10M Over Previous 2 Years	Equity and/or Investment of \$15M Over Previous 2 Years
Project Scope	IND-enabling Preclinical and Clinical Stage Activities	Clinical Stage Activities (including support activities such as manufacturing costs incurred during the project period)

\*In certain extraordinary circumstances, a Track A award may be made up to \$15M.

The objective of a **Strategic Partnership III Track A Award (RFA13-03A)** will be to achieve, in 4 years or less, the completion of a clinical trial under an Investigational New Drug (IND) application filed with the Food and Drug Administration (FDA).

For each project under a **Strategic Partnership III Track B award (RFA13-03B)**, the objective will be to provide, in 4 years or less, evidence of biological activity/efficacy and safety in humans by completing a Phase 1 or Phase 2 clinical trial for a stem cell-based therapy. Achievement of this objective is synonymous with achievement of the Major Development Milestone for the project.

Please click on the links below for RFA 13-03A and RFA 13-03B for full details.

RFA 13-03A: CIRM Strategic Partnership III Awards Track A

RFA 13-03B: CIRM Strategic Partnership III Awards Track B

CIRM has conducted a webinar for prospective applicants on August 7, 2013 at 11 am -12 noon (PDT).

Questions & Answers can be viewed [here](#).

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